Overview of Shared Decision Making

For the online webcast: *Please submit your questions to the panel via the chat box. The online hosts will be collecting the questions during the session to be brought to the panel moderator during the panel discussion.*

OVERVIEW OF SHARED DECISION MAKING

THE PINNACLE OF PATIENT-CENTERED CARE

INFORMED MEDICAL DECISIONS FOUNDATION
Partnerships for Quality Care

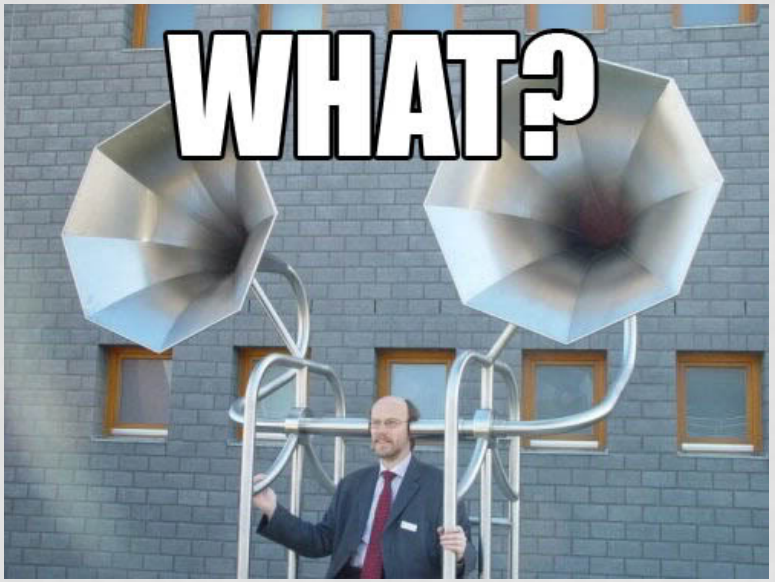
CDRH Patient Preference Initiative Workshop

Michael J Barry, President

September 19 , 2013

FOUNDATION MISSION

- The mission of the Foundation is to inform and amplify the patient's voice in health care decisions



PRINCIPLES THAT GUIDE OUR WORK

We believe patients should be:

Supported and encouraged to participate in their health care decisions

Fully informed with accurate, unbiased and understandable information

Respected by having their goals and concerns honored

IS INFORMED CONSENT "REAL?"

- In a survey of consecutive patients scheduled for an elective coronary revascularization procedure at Yale New Haven Hospital in 1997-1998:
  - 75% believed PCI would help prevent an MI.
  - 71% believed PCI would help them live longer.

Holmboe ES. *JGIM*. 2000; 15:362

IS INFORMED CONSENT "REAL?"

- While even through the latest meta-analysis in 2009 (61 trials and 25,388 patients):
  - "Sequential innovations in catheter-based treatment for non-acute coronary artery disease showed no evidence of an effect on death or myocardial infarction when compared to medical therapy."

Trikalinos TA. *Lancet*. 2009; 373:911.

IS INFORMED CONSENT "REAL?"

- In a survey of consecutive patients consented for an elective coronary angiogram and possible percutaneous coronary intervention at Baystate Medical Center in 2007-2008:
  - 88% believed PCI would help prevent an MI.
  - 76% believed PCI would help them live longer.

Rothberg MB. *Annals Intern Med.* 2010; 153:307.

ARE PATIENTS INFORMED AND INVOLVED?

Question	Percent Who Answered Correctly
How many people	
… get pain relief from joint replacement surgery	28
… experience a surgical complication (e.g. wound infection)	46
… will have replacement last at least 20 years	15
How long most people require to return to normal activity	39

The Decisions Study. Medical Decision Making 2010; 30 supplement 1

ARE PATIENTS INFORMED AND INVOLVED?

Patient Recollection of Decision Making Process	PCa Surgery % (n=685)	CA Stent % (=472)
Talked most with specialist (rather than PCP)	83	86
Doctor discussed reasons for surgery	95	77
Doctor discussed reasons might not want surgery	63	19
Doctor discussed any alternative as serious option	64	10
Doctor asked about your preference for Rx	76	16

Fowler et al, JGIM 2/28/12

TOP THREE GOALS AND CONCERNS FOR BREAST CANCER DECISIONS

Condition: Goal	Pat	Prov	p
Keep your breast?		71%	
Live as long as possible?		96%	
Look natural without clothes		80%	
Avoid using prosthesis		0%	

KR Sepucha et al/Pt Education and Counseling 73(2008)504-10

TOP THREE GOALS AND CONCERNS FOR BREAST CANCER DECISIONS

Condition: Goal	Pat	Prov	p
Keep your breast?	7%	71%	P<0.01
Live as long as possible?	59%	96%	P=0.01
Look natural without clothes	33%	80%	P=0.05
Avoid using prosthesis	33%	0%	P<0.01

KR Sepucha et al/Pt Education and Counseling 73(2008)504-10

THE SILENT MISDIAGNOSIS

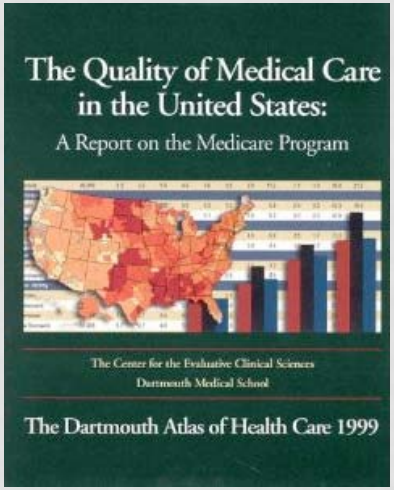
"Many doctors aspire to excellence in diagnosing disease. Far fewer, unfortunately, aspire to the same standards of excellence in diagnosing what patients want."

Mulley A, Trimble C, Elwyn G. Patients' preferences matter: stop the silent misdiagnosis. 367 London: King's Fund; 2012

FORCES SUSTAINING UNWANTED PRACTICE VARIATION

Patients:

Making Decisions in the Face of Avoidable Ignorance



Clinicians:

Less than optimal "Diagnosis" of Patients' Preferences

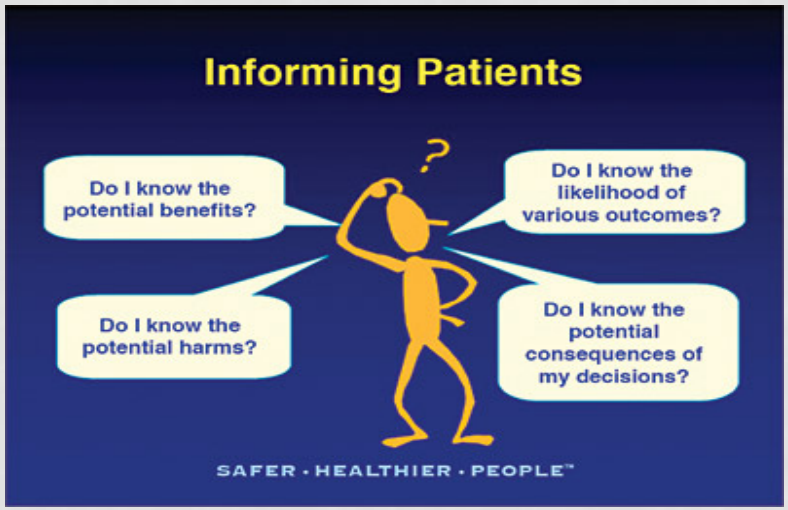
Poor Decision Quality
Unwanted Practice Variation

WHAT IS GOOD MEDICAL CARE?

- It is not just about doing things *right*
- It is also about doing the *right thing*
- Proven effective care: For some medical problems, there is one best way to proceed
- Preference-sensitive care: For many and perhaps most medical problems, there is more than one reasonable option

SHARED DECISION MAKING MODEL

- Key characteristics:
  - At least two participants (clinician & patient) are involved
  - Both parties share information
  - Both parties take steps to build a consensus about the preferred treatment
  - An agreement is reached on the treatment to implement



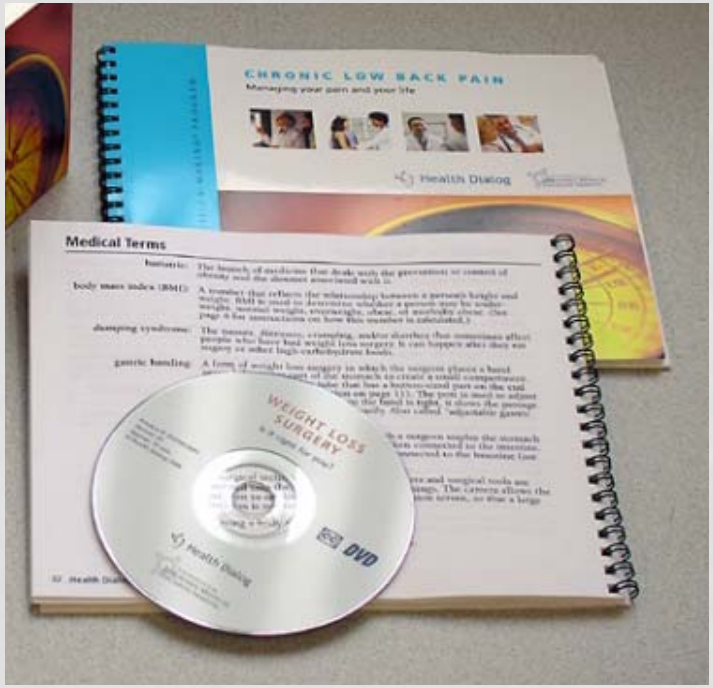
Charles C. *Soc Sci Med.* 1997; 44:681

PATIENT DECISION AIDS CAN HELP!

- Tools designed to help people participate in decision-making
- Provide information on the options
- Help patients clarify and communicate the values they associate with different features of the options

PATIENT DECISION AIDS: TOOLS TO FACILITATE SDM

- Describe a specific condition
- Present information organized around specific decisions
- Strive to keep information accessible (charts, graphs) and balanced
- Encourage patients to interpret information in context of their own goals and concerns
- Engage viewers with real patient stories
- Advise patients to make decisions with their physician



COCHRANE REVIEW OF DECISION AIDS

- In 86 trials in 6 countries of 34 different decisions, use has led to:
  - Greater knowledge
  - More accurate risk perceptions
  - Lower decision conflict
  - Greater participation in decision-making
  - Fewer people remaining undecided

Stacey et al. *Cochrane Database of Systematic Reviews.* 2011, Issue 10. Art. No.: CD001431.

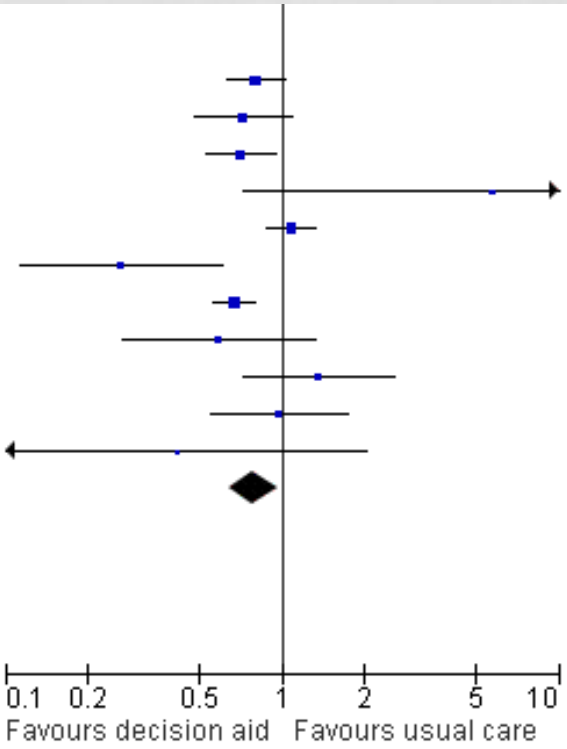
CHOICE OF ELECTIVE SURGERY

1.7.2 Intention to treat analysis

Kennedy 2002	82	300	101	298	15.2%	0.81 [0.63, 1.03]
Bernstein 1998	25	65	28	53	11.2%	0.73 [0.49, 1.09]
Morgan 2000	45	120	63	120	14.0%	0.71 [0.54, 0.95]
Murray 2001a	6	57	1	55	0.9%	5.79 [0.72, 46.54]
Vuorma 2003	98	184	88	179	16.2%	1.08 [0.89, 1.32]
Whelan 2004	6	94	26	107	4.6%	0.26 [0.11, 0.61]
Auvinen 2004	60	104	91	106	16.7%	0.67 [0.56, 0.81]
Barry 1997	8	104	16	123	4.9%	0.59 [0.26, 1.33]
Schwartz 2009	18	100	15	114	6.9%	1.37 [0.73, 2.57]
Tiller 2006	18	68	17	63	7.9%	0.98 [0.56, 1.73]
Vodermaier 2009	2	39	5	41	1.6%	0.42 [0.09, 2.04]
Subtotal (95% CI)		**1235**		**1259**	**100.0%**	**0.79 [0.64, 0.97]**
Total events	368		451			

Heterogeneity: Tau² = 0.06; Chi² = 27.70, df = 10 (P = 0.002); I² = 64%

Test for overall effect: Z = 2.20 (P = 0.03)



A CHORUS OF VOICES CALLING FOR SDM

NPSF
National Patient Safety Foundation®

AMA
AMERICAN MEDICAL ASSOCIATION

national partnership for women & families

AARP

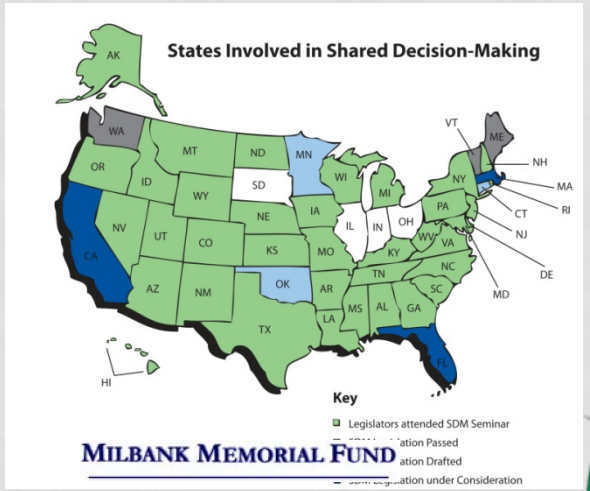
ABIM FOUNDATION

National Priorities Partnership
Convened by the National Quality Forum

NQF
THE NATIONAL QUALITY FORUM

Patient-Centered Primary Care COLLABORATIVE

National Business Group on Health



American Cancer Society®

FOUNDATION FOR INFORMED MEDICAL DECISION MAKING

SDM: IMPLEMENTATION NEEDS

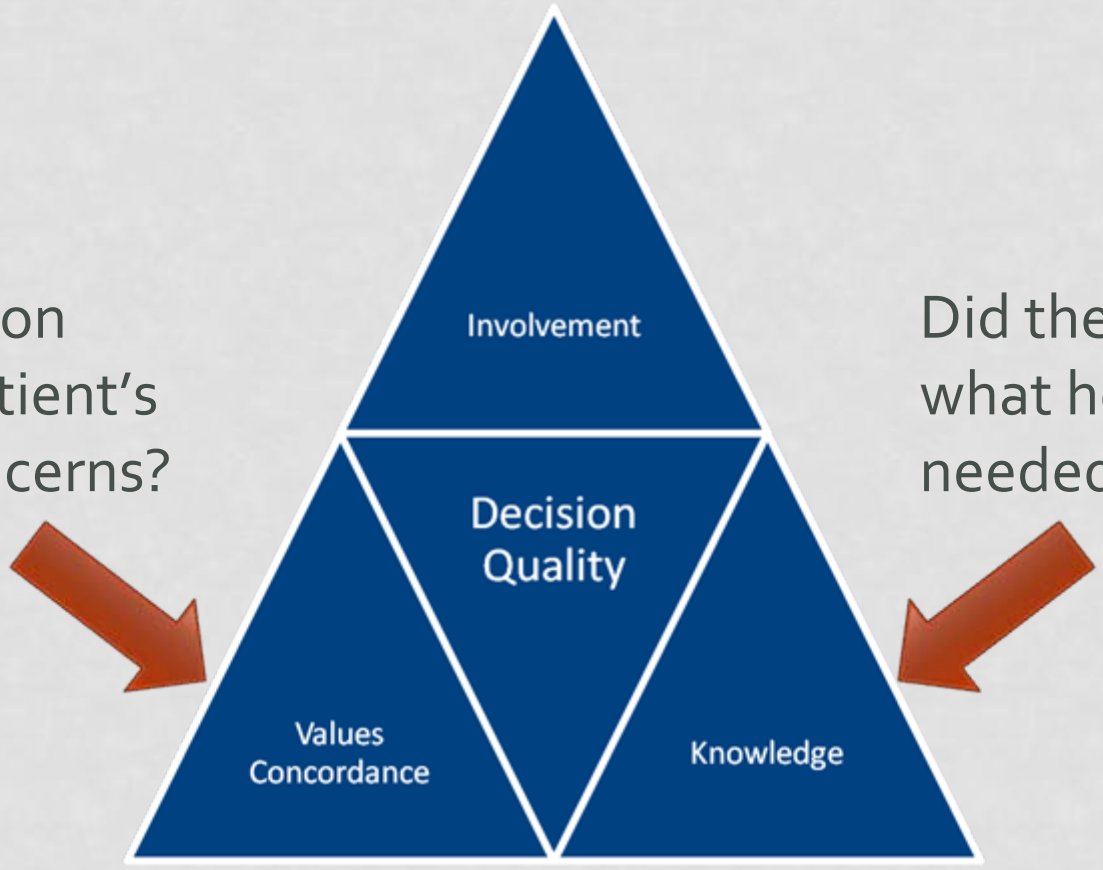
- Patients interested in being informed and activated
- Practical protocols for routine use of decision support tools
- Health care systems with incentives for good "decision quality" rather than simply "more is better"
- Clinicians and hospitals receptive to patient participation

Did the patient know a decision was being made?

Did the patient know the pros and cons of the treatment options?

Did the provider elicit the patient's preferences?

Did the decision reflect the patient's goals and concerns?

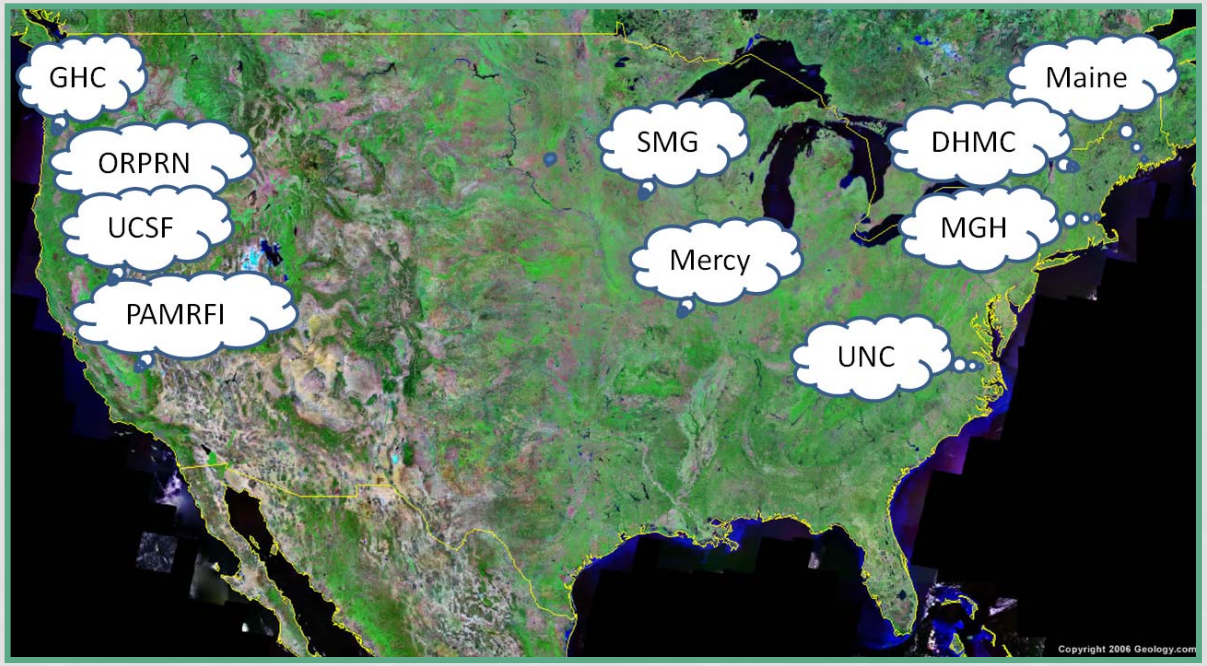


Did the patient know what he or she needed to know?

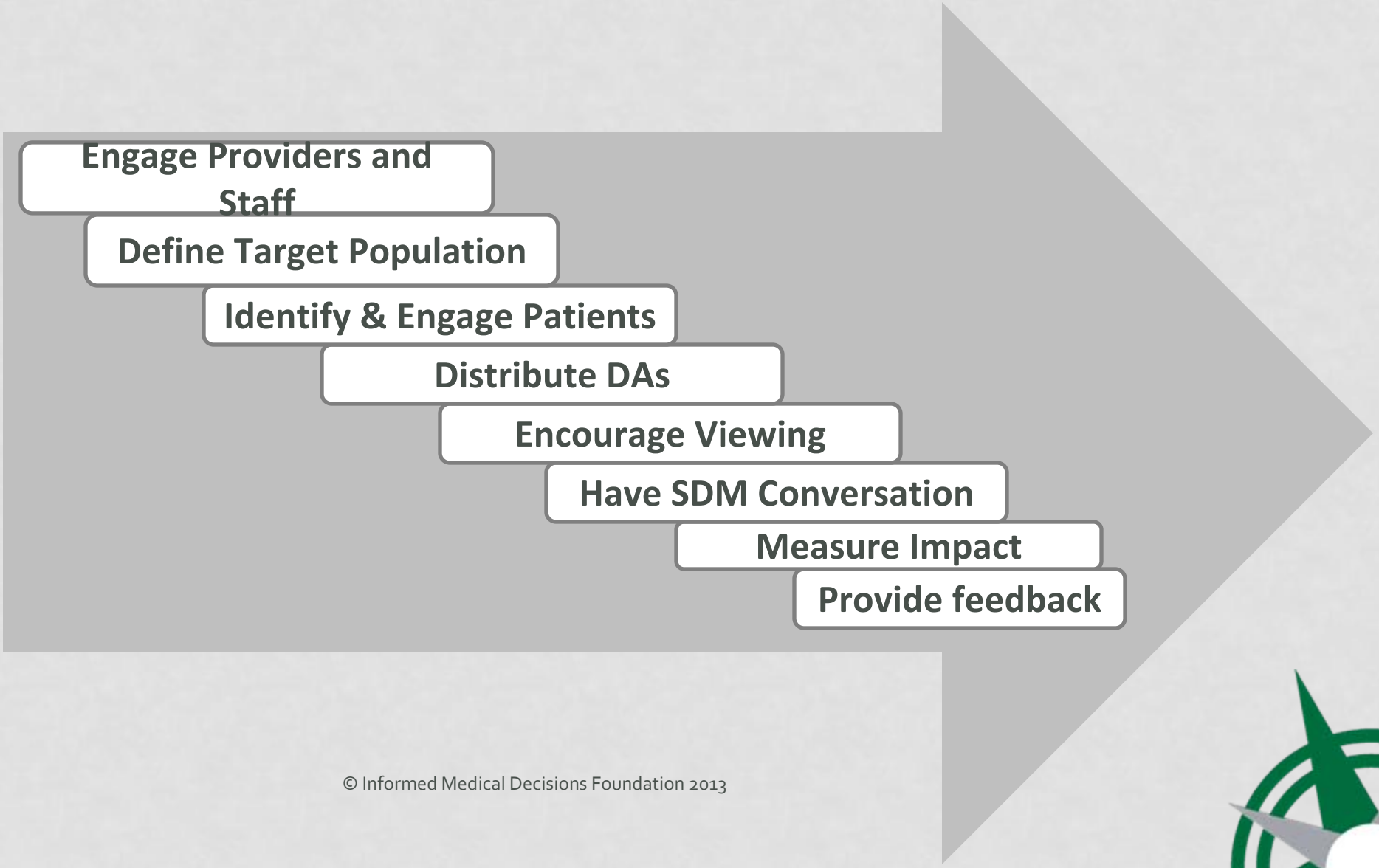
Sepucha KR, et al. *Health Aff (Millwood).* 2004; Suppl Web Exclusives:VAR54-62.

DEMONSTRATION SITE PROGRAM

Objective: to demonstrate that the use of patient decision aids and the process of shared decision making can effectively and efficiently become part of day-to-day care

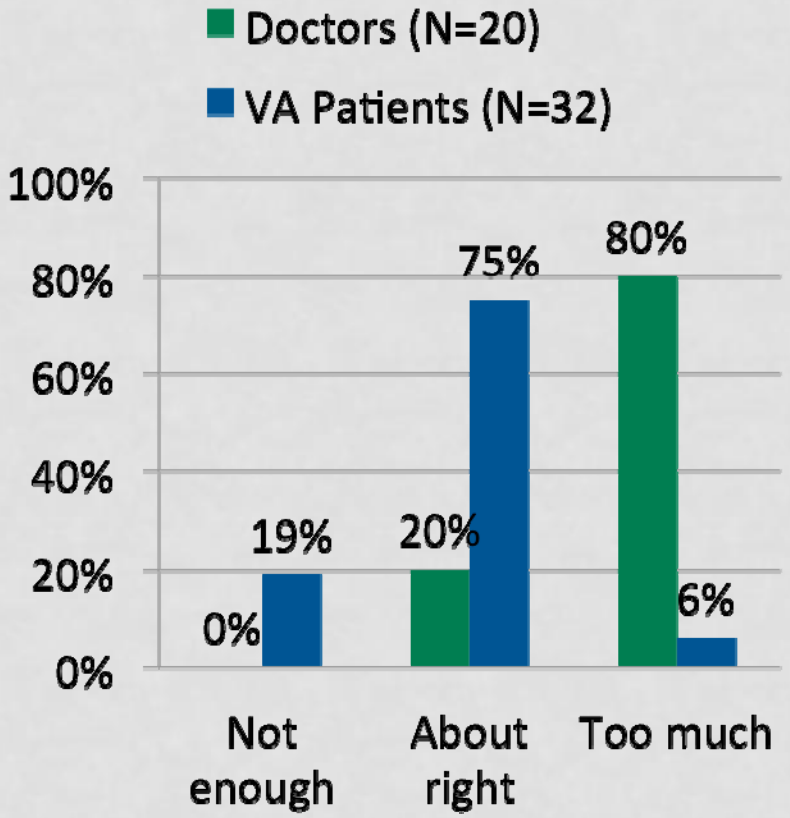


Key Objectives For Successful Implementation of SDM with DAs

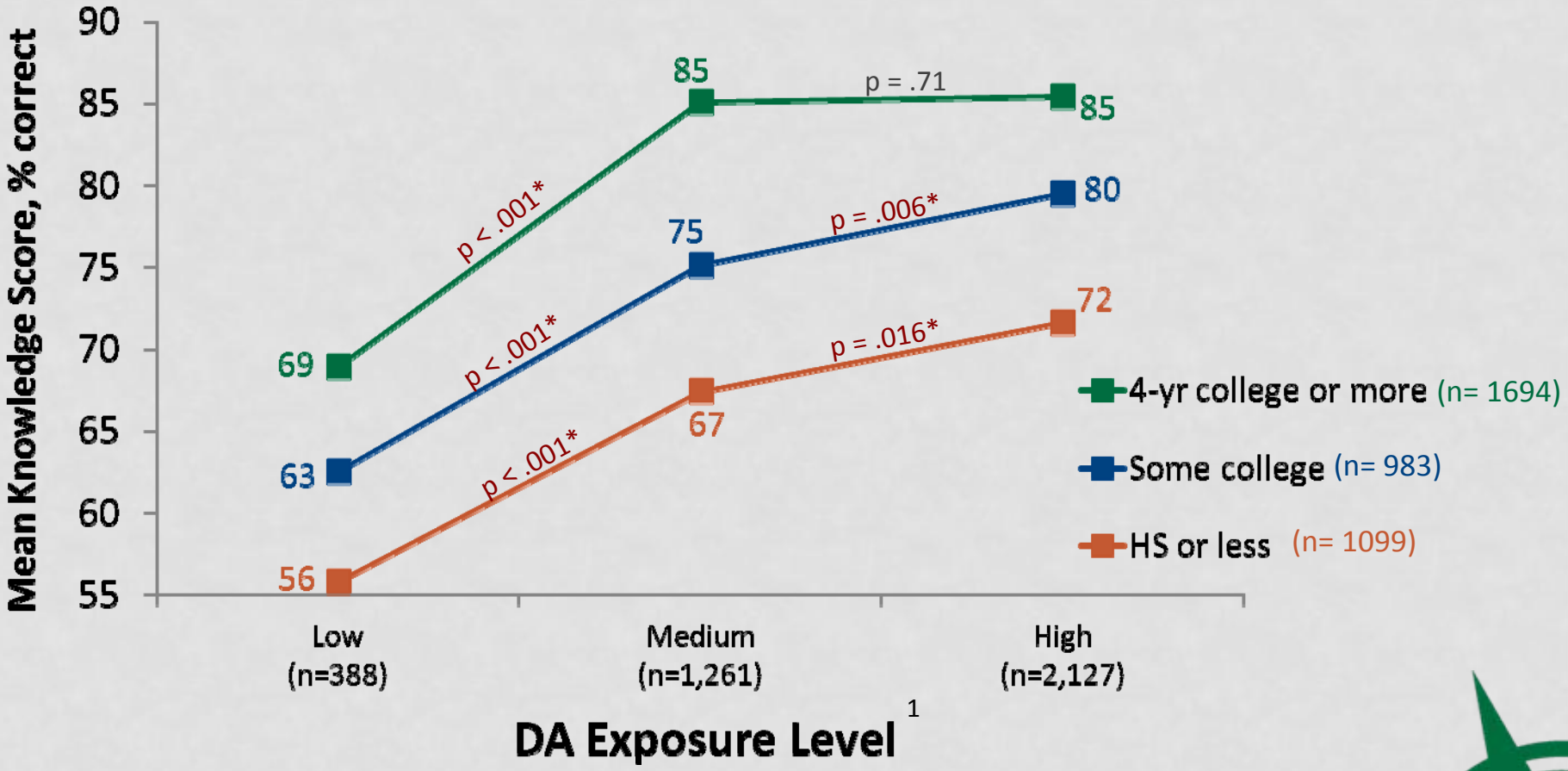


TESTING OUR FIRST 30-MINUTE BPH PROGRAM

How would you rate the amount of information?



KNOWLEDGE SCORES BY DA EXPOSURE LEVEL: EDUCATION LEVEL

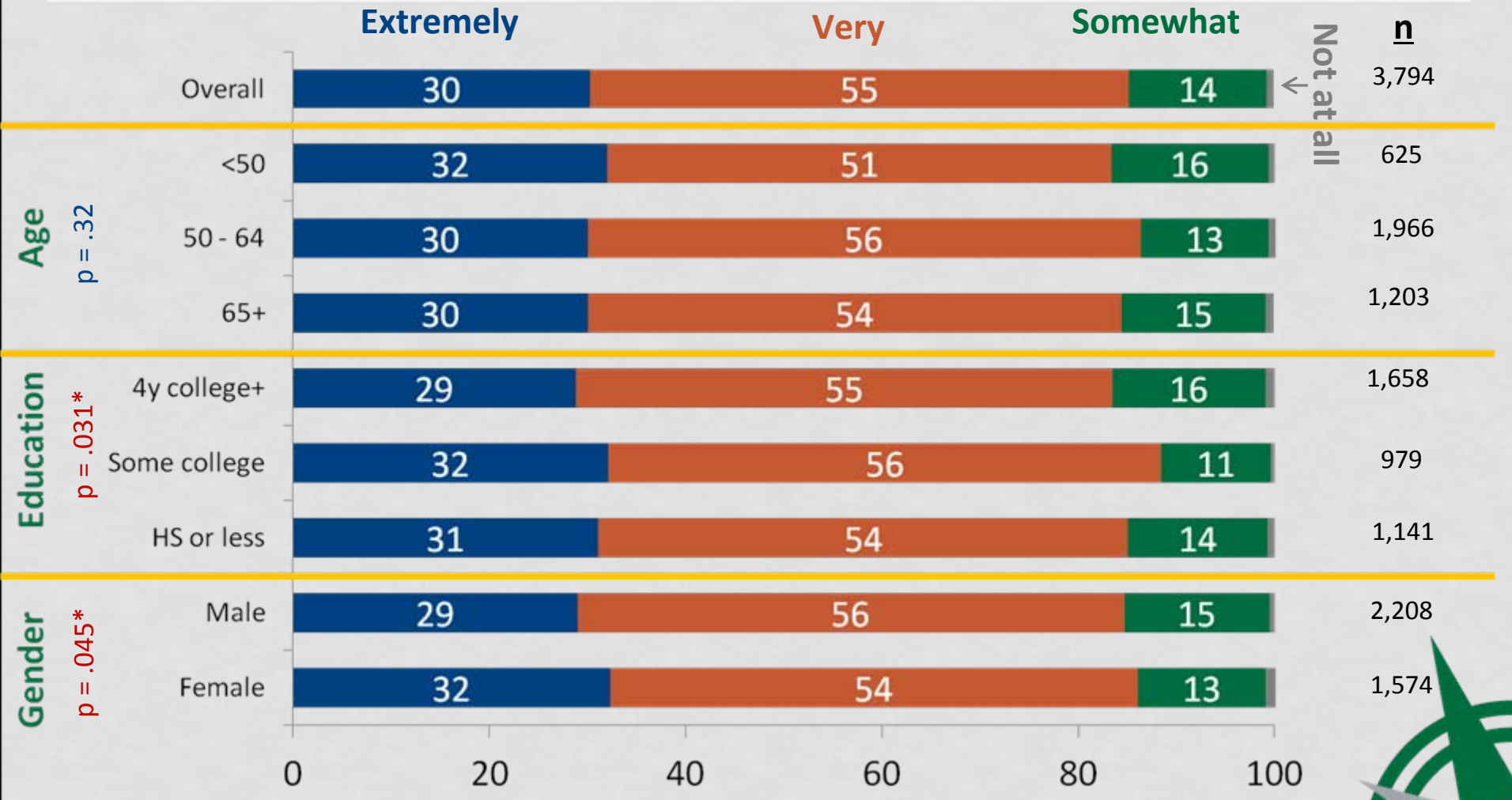


Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)

*All significance tests are independent sample t-tests; * = Difference in means is statistically significant ($p \leq 0.05$)

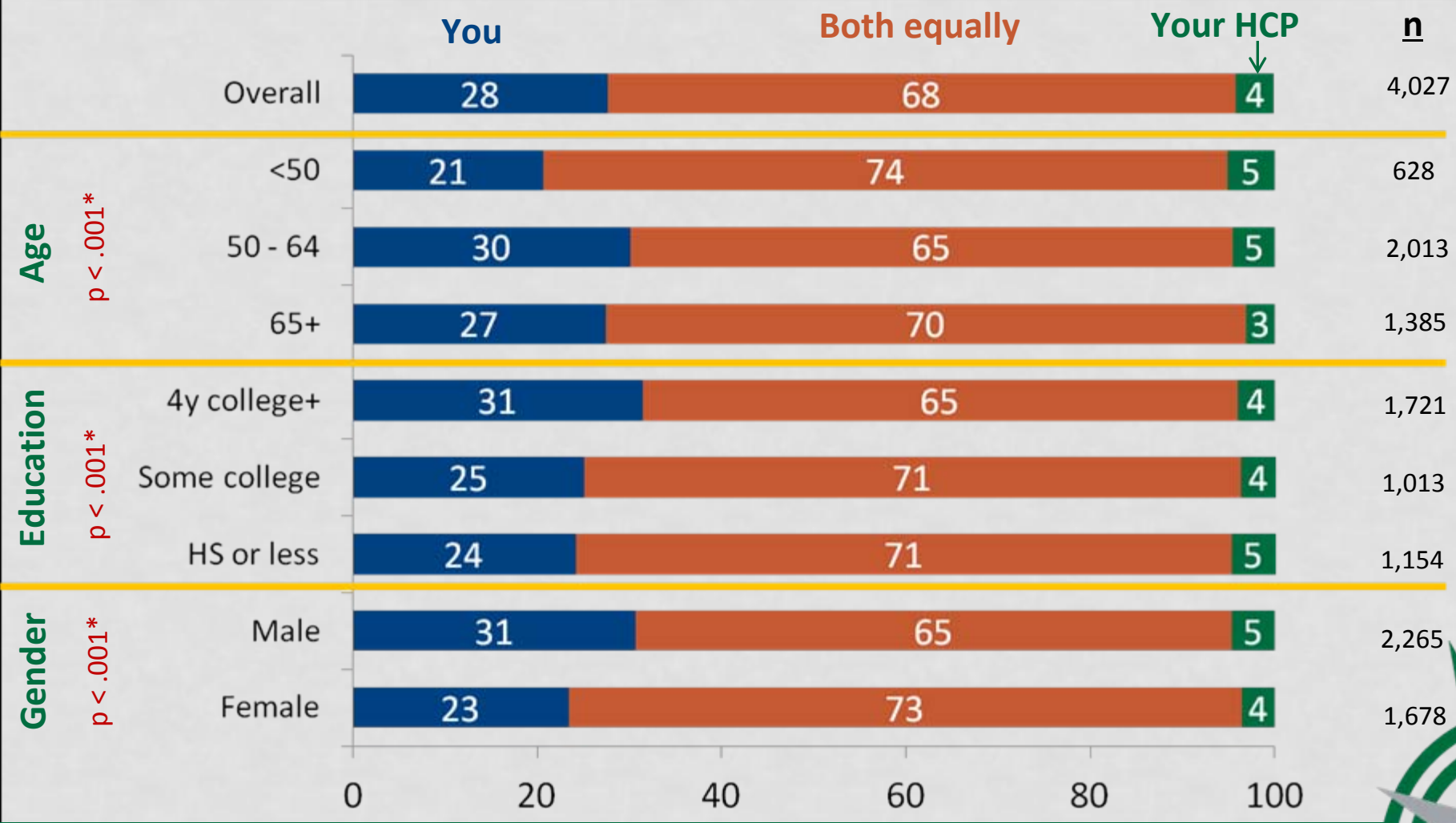
[1]DA Exposure Level definition: Low = none of either OR some of both OR (some of one AND none of the other); Medium = Most of both OR (most or all of one AND (none or some of the other)); High = All of both OR (all of one AND most of the other)

IMPORTANCE RATINGS BY DEMOGRAPHIC GROUP



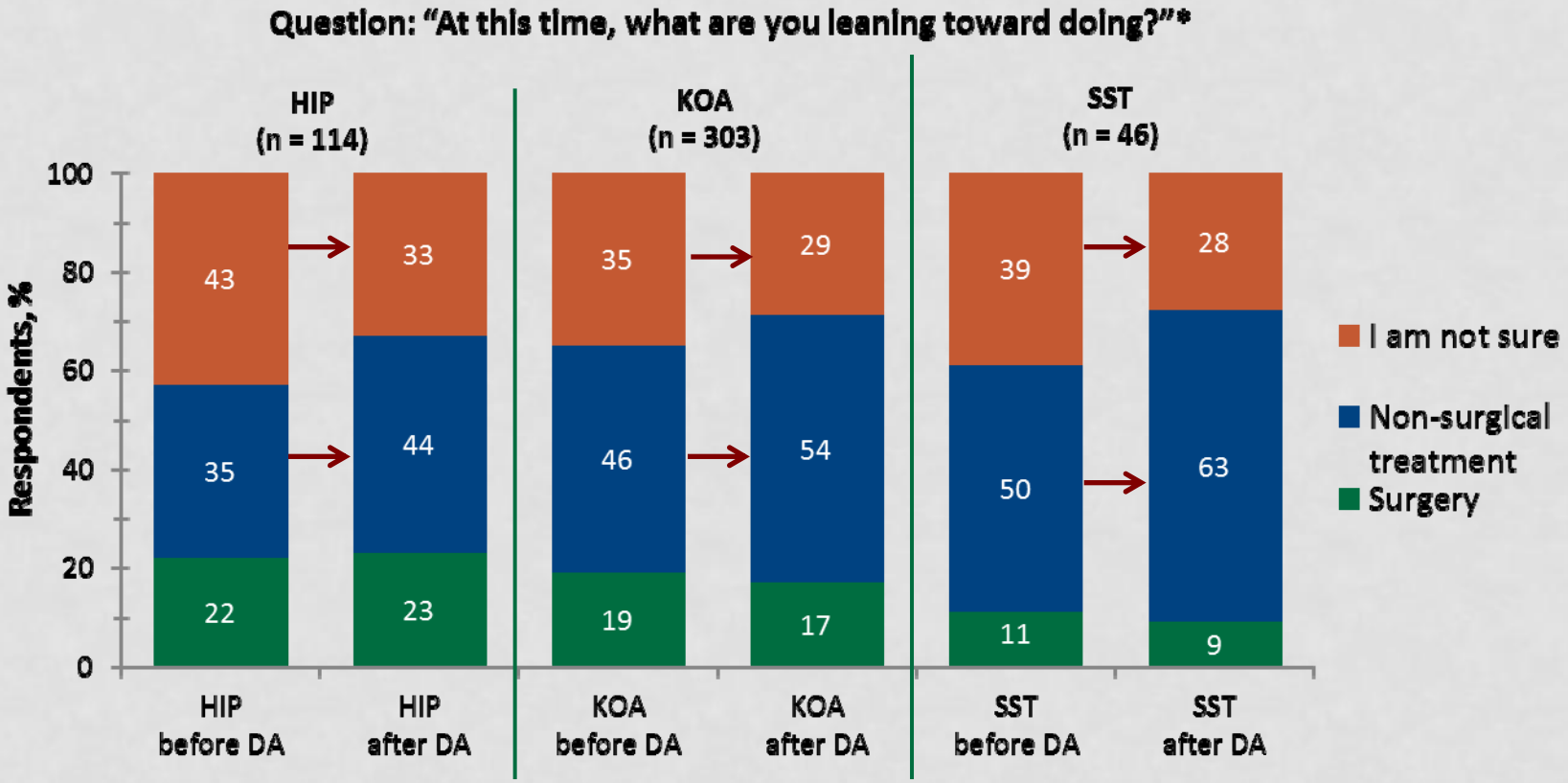
ncludes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)
**Statistically significant (p ≤ 0.05) (Chi square test)

DECISION ROLE PREFERENCES BY DEMOGRAPHIC GROUP



Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)
*Statistically significant ($p \leq 0.05$) (Chi square test)

UNDECIDED PEOPLE TEND TO MOVE TOWARD NON-SURGICAL OPTIONS



Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 5/16/12 (unweighted)
*Includes only respondents who answered the question both before and after

HIP AND KNEE DECISION AIDS AT GROUP HEALTH

- Introduced pDAs for hip/knee arthroscopy candidates in 2009
- Reached 28% of eligible knee (N=3510)and 41% of hip patients (N=820)
- Over 6 months:
  - 38% fewer knee replacements
  - 26% fewer hip replacements
  - 12-21% lower costs

GroupHealth®

Arterburn D, et al. Health Affairs 2012; 31(9)

THE HVHC CMMI PROJECT

- CMMI Innovation Grant
- "HVHC: Engaging Patients to Meet the Triple aim"
- 16 member systems (~50 million served) will deploy "patient and family activators"
- Coaching and pDAs for DM, heart failure, back surgery, hip/knee arthroplasty

THE DARTMOUTH INSTITUTE
FOR HEALTH POLICY & CLINICAL PRACTICE

HVH
HIGH VALUE HEALTHCARE COLLABORATIVE

THANK YOU!

MBARRY@IMDFOUNDATION.ORG
WWW.INFORMEDMEDICALDECISIONS.ORG

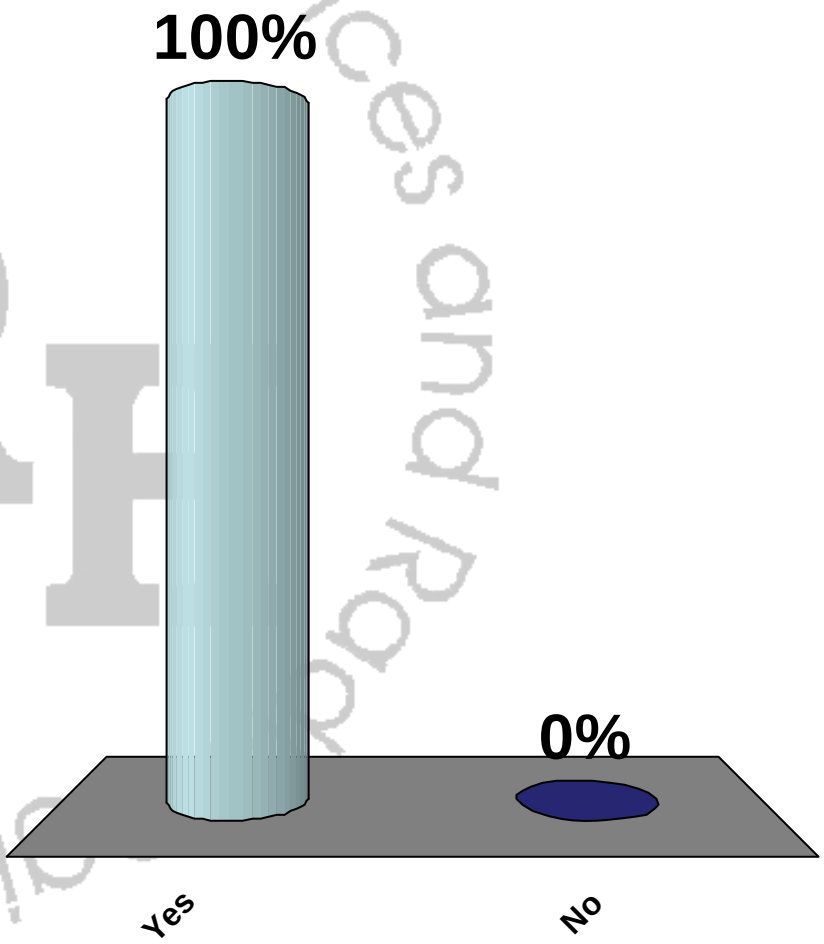
Day Two Wrap Up
Strategies Going Forward

Michelle McMurry-Heath, M.D., Ph.D.

1. Audience Participation
2. Panelist Summaries
3. Steps Going Forward

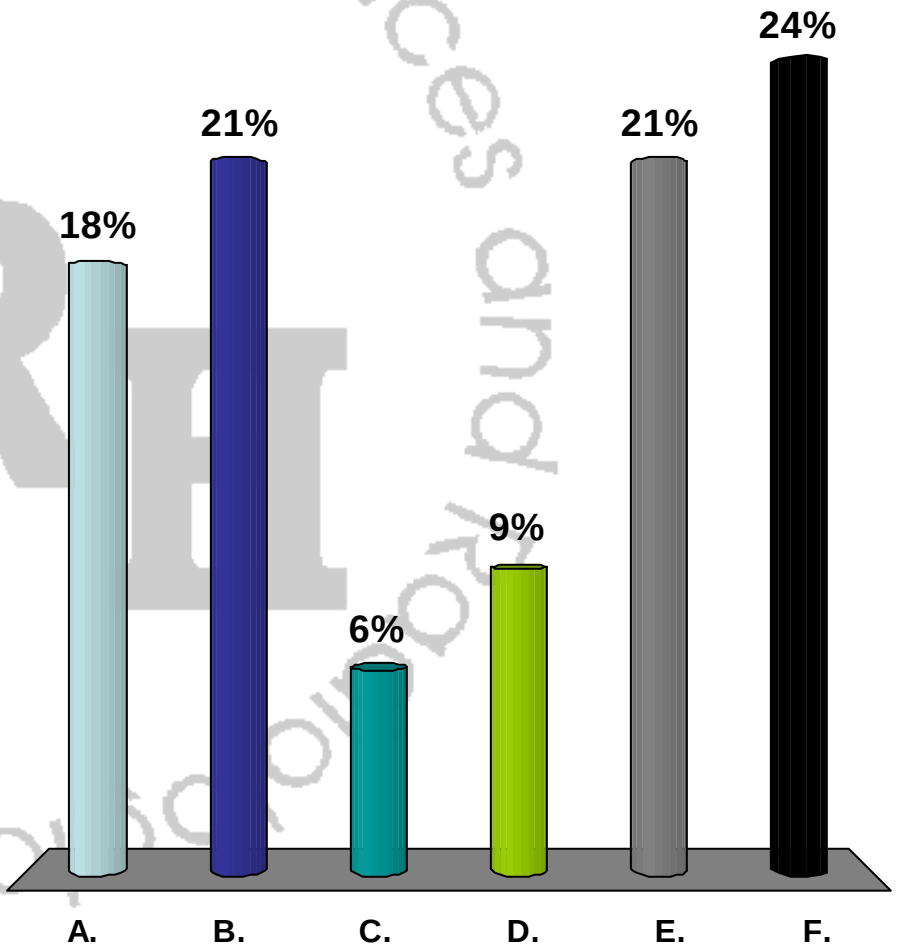
Is your clicker working?

A. Yes
B. No



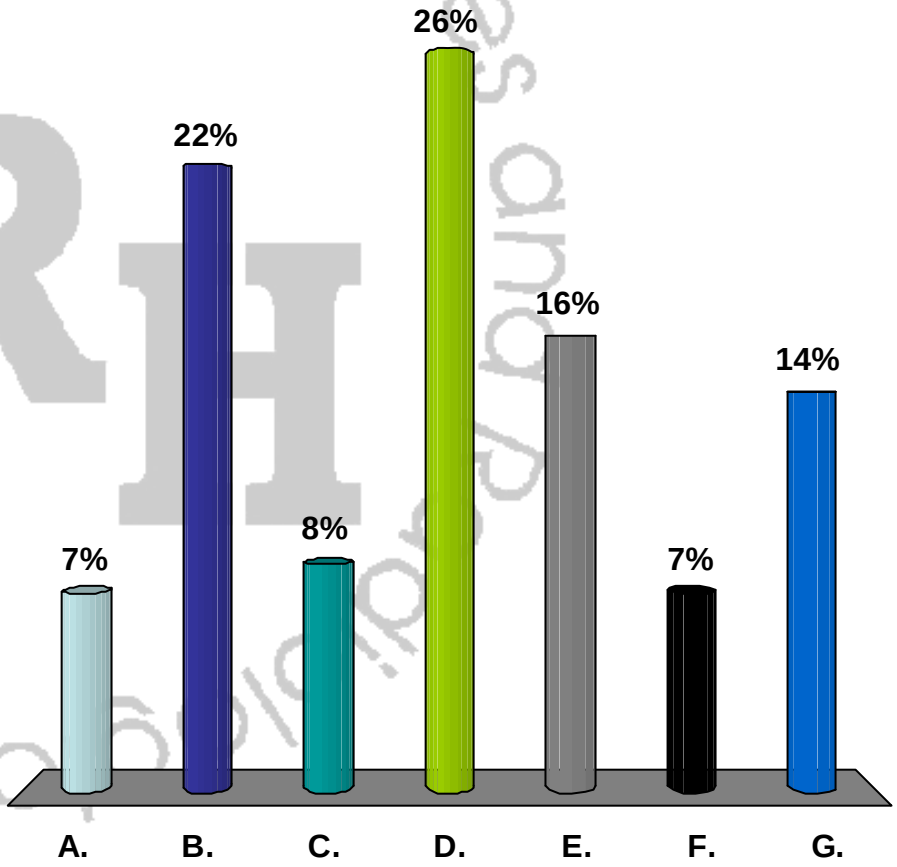
Please identify your affiliation:

A. Patient/ Patient advocacy group
B. Professional Society
C. Research/ Academia
D. Provider/Clinician
E. Industry
F. Federal Agency



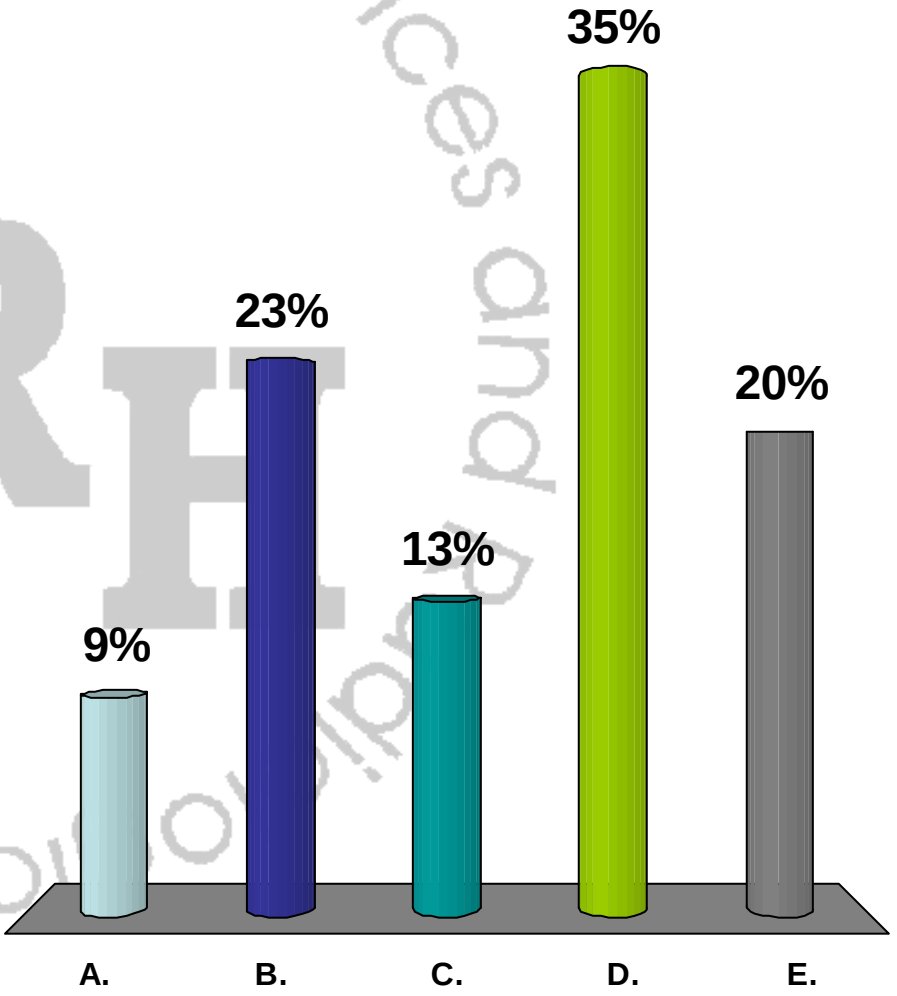
Where in the medical device total product lifecycle (TPLC) could you see patient preference information best utilized?

A. Discovery & ideation
B. Invention & prototyping
C. Pre-clinical
D. Clinical trials
E. Regulatory decision
F. Product launch
G. Post-market monitoring



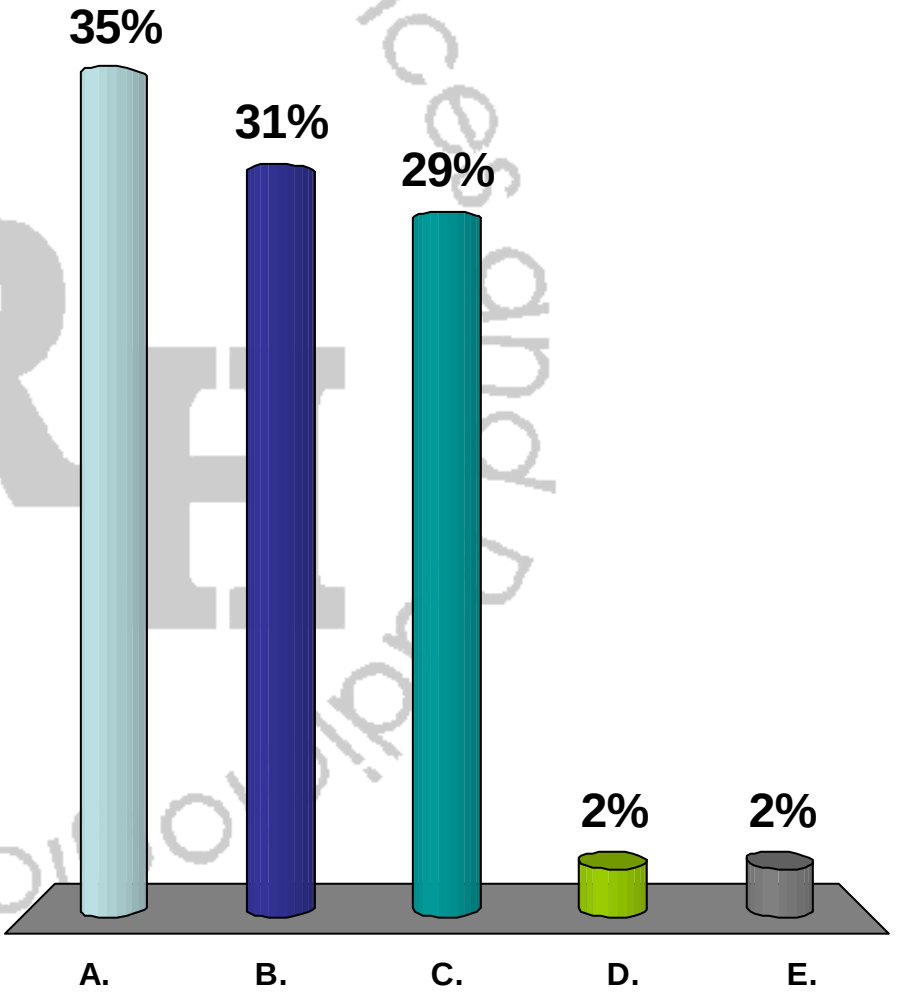
Who is best situated to collect patient preference information?

A. Academia
B. Industry
C. Clinicians
D. Patient Groups
E. Regulators



Where and how should patient preference information be communicated?

A. Decision-making conversation
B. Device labeling
C. Health communication
D. FDA Website
E. Other



Day Two Wrap Up
Strategies Going Forward

Michelle McMurry-Heath, M.D., Ph.D.

1. Audience Participation
2. Panel Summaries
3. Steps Going Forward

Moderator: ***Michelle McMurry-Heath, M.D., Ph.D.***
Associate Director for Science
CDRH/Office of the Center Director

Panel: ***Bray Patrick-Lake, M.F.S.***
Clinical Trials Transformation Initiative (CTTI)

Diana Salditt
Medtronic, Inc.
AdvaMed

F. Reed Johnson, Ph.D.
Research Triangle Institute (RTI-Health Solutions)

Gregg Rosenberg, Ph.D.
WiserTogether, Inc.

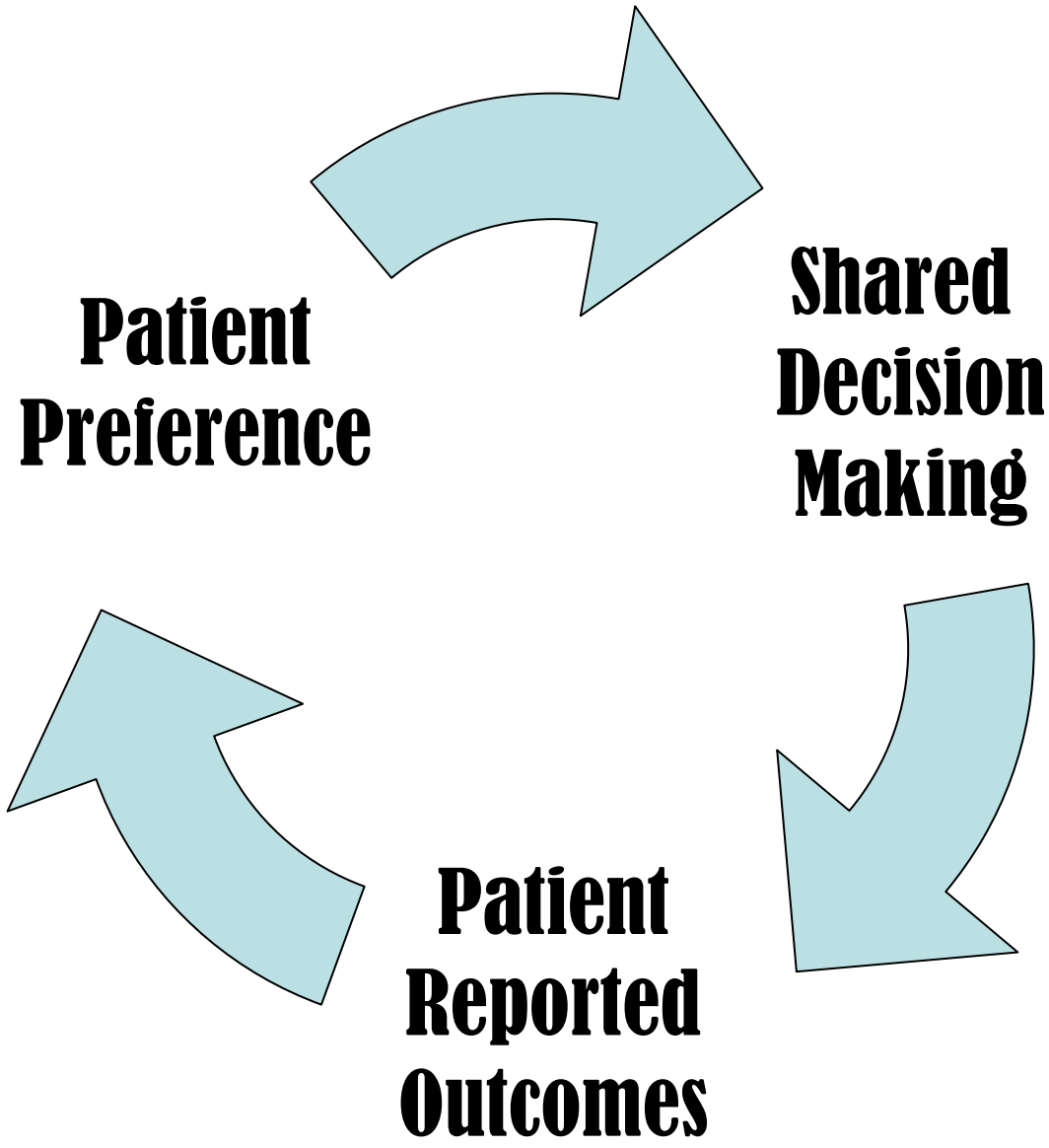
William Murray
Medical Device Innovation Consortium (MDIC)

PATIENT PREFERENCE AND MEDICAL DEVICES

What Matters?

- ✓ Patients
- ✓ Context
- ✓ Methods
- ✓ B-R Ratio
- ✓ The TPLC
- ✓ Partnerships
- ✓ Risk Communications

Total Patient Lifecycle



Thank you for attending.

Please submit any additional questions and comments to the public docket.

Please remember to return your badges and clickers.